

Academy of Medical Sciences' statement on the guidance documents for implementation of the Clinical Trials Regulation

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The Academy of Medical Sciences promotes advances in medical science, and campaigns to ensure that these are translated into healthcare benefits for society. Our elected Fellowship comprises some of the UK's foremost experts in medical science, drawn from a diverse range of research areas.

Successful European health research relies on an effective clinical trial and regulatory infrastructure. We therefore welcome the public consultation on the guidance for implementation of the Clinical Trials Regulation (CTR).

The CTR must continue to support this outstanding research ecosystem. In particular, we are highly supportive of the establishment of a risk proportionate approach to clinical trials, and this was highlighted as a key recommendation in our 2011 report on '*A new pathway for the regulation and governance of health research*'.¹ The regulatory guidance should support the implementation of regulatory requirements, continuing to protect patient safety whilst not placing any unnecessary burdens on the research and development process.

We welcome future opportunities to involve our Fellowship in the development of the regulatory guidance and the wider clinical trial infrastructure in Europe.

¹ Academy of Medical Sciences (2011). *A new pathway for the regulation and governance of health research*. <http://www.acmedsci.ac.uk/download.php?f=file&i=13646>